

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MERCK & CO., INC.,	:	
	:	
Plaintiff,	:	CIVIL ACTION
	:	NO. 97-CV-4241
	:	
v.	:	
	:	
MYLAN PHARMACEUTICALS, INC.,	:	
	:	
Defendant.	:	
	:	

M E M O R A N D U M

EDUARDO C. ROBRENO, J.

AUGUST , 1998

I. INTRODUCTION

This is an action brought by plaintiff Merck Pharmaceuticals against defendant Mylan Pharmaceuticals for patent infringement of its SINEMET CR tablets, designed for use in the treatment of Parkinson's disease. Merck alleges that, under the well-established patent law doctrine of equivalents, Mylan's filing of an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration, setting forth a generic formulation of Merck's products infringed upon United States Patents No. 4,832,957 (the "'957 patent") and No. 4,900,755 (the "'755 patent"). Defendant Mylan has now moved for summary judgment on the grounds that the prior art doctrine and prosecution history estoppel limit the scope of Merck's patents and, as a result of

these limitations, Merck is precluded from asserting infringement by Mylan's product under the doctrine of equivalents. For the reasons which follow, the Court will grant summary judgment in favor of Mylan and against Merck.

II. BACKGROUND¹

In the 1980's, Merck began development of a product intended to provide a more effective treatment of Parkinson's disease. The proposed product involved the controlled release of the two active ingredients already in the market, levodopa and carbidopa. On June 16, 1986, Merck filed its original patent application for the proposed product which included, as its broadest claim, the following:

A controlled release oral dosage formulation comprising a uniform dispersion of 5-300 mg of carbidopa, 2-1200 mg of levodopa, 0-25 mg of a tablet lubricant and optionally a pharmaceutically acceptable dye, in a polymer vehicle comprising 0-120 mg of a water soluble polymer and 0-120 mg of a less water soluble polymer, with the proviso that both polymers are not 0 mg, whereby following administration the carbidopa and levodopa are released slowly and simultaneously from the formulation.

DE at A106.² The Patent and Trademark Office ("PTO") rejected

¹ The following brief summary of the undisputed facts are taken from the parties' briefs and evidentiary submissions. To the extent that the undisputed facts are subject to conflicting interpretation, under the summary judgment standard, the Court has viewed the facts in the light most favorable to Merck, the non-movant.

² For ease of discussion, plaintiff's exhibits will be referred to as "PE" plus the page number, defendant's exhibits as "DE" plus the page number and defendant's supplemental exhibits as "SDE" plus the page number. Further, cites to the respective

all of these claims, in part, as being obvious over the prior art. Specifically, the patent examiner referenced, inter alia, the Sheth patent (U.S. Patent No. 4,424,235), which discloses a hydrodynamically-balanced (i.e. floating) controlled release formulation of carbidopa and levodopa in a polymer vehicle³, and

briefs will be as follows: Defendant's Motion for Summary Judgment based on Prior Art - "PAMotion", Defendant's Motion for Summary Judgment based on Prosecution History - "PHMotion", Plaintiff's Response - "Response", Defendant's Reply on the Prior Art Issue- "PAREply", and Defendant's Reply on the Prosecution History Issue - "PHReply".

³ Claim one of the Sheth '235 patent discloses the following:

A hydrodynamically balanced controlled release composition comprising

(a) as the active ingredient, an amount of L-Dopa which is effective in achieving desired levels of L-Dopa in the blood and an amount of a decarboxylase inhibitor selected from the group consisting of N¹-dl-seryl-N² (2,3,4, trihydroxybenzyl) hydrazine hydrochloride, 6-(3,4-dihydroxyphenyl)- α -hydrazino- α -methyl propionic acid, m-hydroxybenzylhydrazine and 6-methyldopa, which is effective for the amount of L-dopa in the composition and wherein the ratio of L-dopa to decarboxylase inhibitor ranges from about 4:1 to about 10:1.

(b) in percents by weight based on the total weight of the composition or mixture of hydrocolloids selected from the group consisting of acacia, gum tragacanth, locust bean gum, guar gum, karaya gum, agar, pectin, carrageen, soluble and insoluble alginates, methylcellulose, hydroxy-propyl methylcellulose [HPMC], hydroxypropylcellulose [HPC], sodium carboxymethylcellulose, carboxypolymethylene, gelatin, casin, zein and bentonite; up to about 60% of a fatty material . . . an up to about 80% of edible inert pharmaceutical adjunct materials

Whereby said composition , when used in capsule or tablet form, is hydrodynamically balanced so that, upon contact with gastric fluid, aid capsule or tablet acquires and maintains a bulk density of less than one

the Schor patent (U.S. Patent No. 4,389,393), which discloses a controlled release formulation of any medicament containing the combination of hydroxypropylmethylcellulose [HPMC] and another cellulose⁴. Further, the patent examiner required Merck to "elect a single disclosed species." DE at A122. This election is permitted under 35 U.S.C. § 121, which provides that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. § 121. Merck failed to respond to the PTO's rejection. As a result, pursuant to the PTO's Notice of Abandonment, the application was deemed

thereby being buoyant in the gastric fluid and remaining buoyant in the gastric fluid of the stomach until substantially all of the active ingredients contained therein have been released.

DE at A33.

⁴ The Schor '393 patent discloses the following:

A carrier base material combined with a therapeutically active medicament and shaped and compressed to a solid unit dosage form having a regular and prolonged release pattern upon administration, the carrier base material being one or more hydroxypropylmethylcelluloses or a mixture of one or more hydroxypropylmethylcelluloses and up to 30% by weight of the mixture of methyl cellulose, sodium carboxymethylcellulose and/or other cellulose ether, and wherein at least one of the hydroxypropylmethylcelluloses has methoxy content of 16-24 weight-%, a hydroxypropoxyl content of 4-32 weight-% and a number average molecular weight of at least 50,000 and wherein the carrier base material constitutes less than about one third of the weight of the solid unit dosage form.

DE at A33.

abandoned. DE at A126.

On December 11, 1987, Merck filed a second application limiting the scope of its claims. DE at A151-168. Now, instead of seeking coverage of formulations containing any "water soluble" and "less water soluble" polymers, Merck's broadest claim was restricted to a controlled release oral dosage formulation of carbidopa and levodopa in a polymer vehicle comprised of a water soluble polymer selected from a named group and a less water soluble polymer also selected from a named group. Specifically, the claim read as follows:

A controlled release oral dosage formulation comprising a uniform dispersion of 5-300 mg of carbidopa, 20-1200 mg of levodopa, 0-25 mg of a tablet lubricant and optionally a pharmaceutically acceptable dye, in a polymer vehicle comprising 0-120 mg of a water-soluble polymer selected from hydroxypropyl cellulose, hydroxypropylmethylcellulose, polyvinyl pyrrolidone, polyethylene glycol, starch and methyl cellulose and 0-120 mg of a less water-soluble polymer selected from polyvinyl acetate-crotonic acid copolymer, polyvinyl chloride, polyethylene, cellulose acetate, polyvinyl alcohol, polymethyl methacrylate, and ethyl cellulose, with the proviso that both polymers are not 0 mg, whereby following administration the carbidopa and levodopa are released slowly and simultaneously from the formulation.

DE at A167. Again, however, the PTO rejected Merck's claims citing, in part, obviousness over the prior art, including Sheth and Schor. DE at A184-85 The patent examiner also reiterated the requirement that Merck elect a single disclosed species under 35 U.S.C. § 121. DE at 186.

On July 25, 1988, Merck abandoned its second application and filed yet a third application, seeking coverage identical to that

in the second. DE at A210-228. Prior to the PTO's consideration of the third application, Merck filed a preliminary amendment to the third application restricting the amounts of carbidopa and levodopa and limiting the polymer vehicle to two specific polymers. The broadest claim then disclosed:

A controlled release oral dosage formulation comprising a uniform dispersion of 25-100 mg of carbidopa, 100-400 mg of levodopa, 1-10 mg of a tablet lubricant and mixture of those with a pharmaceutically acceptable dye, in a polymer vehicle comprising 5-25 mg of a water soluble hydroxypropyl cellulose polymer [HPC] and 2-50 mg of a less water-soluble polyvinyl acetate-crotonic acid copolymer [PVACA] whereby following administration the carbidopa and levodopa are released slowly and simultaneously from the formulation.

DE at A237-238. Based on this narrower claim, the PTO issued the '957 patent to Merck. DE at A242

On February 24, 1989, after receipt of the '957 patent, Merck filed an application for what is now the '755 patent. DE at A261-280. The broadest claim asserted in this application was identical to the broadest claim described above for the second application in the '957 prosecution.⁵ As it did previously, the PTO rejected Merck's claims as obvious over the prior art including, inter alia, Sheth and Schor. DE at A287-288. Again, the patent examiner also required an election under 35 U.S.C. § 121. DE at 289.

Merck then narrowed its claims to mirror those of the '957

⁵ As Merck explains, the claims of the two patents are similar except that the claims of the '957 patent include a dye and a lubricant while the claims of the '755 do not.

patent, absent the dye and lubricant. DE at A294-295. At that point, it also made the following statements to the PTO:

Applicants take issue with some of the Examiner's characterizations of the references.

Sheth et al (U.S. Patent 4,424,235) does describe a sustained-release combination of levodopa and carbidopa, but the design of the formulation and the components thereof differs from those of the present claims. A single polymer is used in the Sheth formulation selected from a natural gum, methyl cellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose and sodium carboxymethylcellulose. The claimed formulation is a combination of hydroxypropylcellulose and polyvinylacetate-crotonic acid copolymer . . .

. . . The last secondary reference, Schor et al (U.S. 4,389,393), lists a number of medicinal agents deliverable by their claimed formulation, none of which is identified as an anti-Parkinson agent and none of which comprises two active ingredients. Furthermore, their formulation comprises hydroxypropylmethylcellulose primarily as the carrier or optionally

"with about 0 to 30% by weight of the mixture of . . . methylcellulose sodium carboxymethylcellulose or other cellulose either." (Column 4, lines 22-28).

Accordingly, Schor does not suggest the combination of the hydroxypropyl-cellulose and polyvinyl acetate-crotonic acid copolymer as presently claimed as a vehicle for any medicament.

DE at A295-296. On the basis of the amendment, the '755 patent was issued.

In February of 1996, Mylan filed an Abbreviated New Drug Application with the Food and Drug Administration, pursuant to the Hatch-Waxman Act⁶, disclosing a product containing: (a) 200

⁶ The Hatch-Waxman Act, codified in part at 35 U.S.C. §271, inter alia, allows makers of generic drugs to market generic

mg of levodopa and 50 mg of carbidopa; 29.3 mg of HPC polymer and; (c) 12.8 mg of hydroxypropyl methylcellulose (HPMC) polymer. DE at A13-16.

On June 24, 1997, Merck filed a complaint in this Court alleging infringement of both its '755 patent and its '957 patent. The instant action ensued.

III. STANDARD OF REVIEW⁷

Federal Rule of Civil Procedure 56(c) states that summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Williams v. Borough of West Chester, 891 F.2d 458, 463-64 (3d Cir. 1989). A factual dispute is "material" only if it might affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). For there to be a "genuine" issue, a reasonable fact finder must

versions of patented drugs as soon as possible after expiration of the relevant patents, while providing patent holders with limited extensions of patent term in order to recover a portion of the market exclusivity lost during the lengthy process of development and FDA review.

⁷ It is settled that in a patent case, when an issue pertains to a matter not unique to the Federal Circuit's exclusive appellate jurisdiction, the district court should "defer to the discernable law of the regional circuit in which the district court sits." Mars, Incorporated v. Nippon Conlux Kabushiki-Kaisha, 24 F.3d 1368, 1371 (Fed. Cir.1994).

be able to return a verdict (or render a decision) in favor of the non-moving party. Id. On summary judgment, it is not the court's role to weigh the disputed evidence and decide which is more probative. Brewer v. Quaker State Oil Refining Co., 72 F.3d 326, 331 (3d Cir. 1995). Rather, the court must consider the evidence, and all reasonable inferences which may be drawn from it, in the light most favorable to the non-moving party. United States v. Diebold, Inc., 369 U.S. 654, 655 (1962); Tigg Corp. v. Dow Corning Corp., 822 F.2d 358, 361 (3d Cir. 1987); Baker v. Lukens Steel Co., 793 F.2d 509, 511 (3d Cir. 1986). If a conflict arises between the evidence presented by both sides, the court must accept as true the allegations of the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. at 255.

Once the movant has carried its initial burden, Rule 56(e) shifts the burden to the nonmoving party as follows:

When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party.

Fed.R.Civ.P. 56(e). With respect to an issue on which the non-moving party has the burden of proof, the burden on the moving party may be discharged by "showing"--that is, pointing out to the district court-- that there is an absence of evidence to support the nonmoving party's case. Celotex Corp. v. Catrett,

477 U.S. 317, 325 (1986).

IV. DISCUSSION

A. Infringement Under the Doctrine of Equivalents

Under well-established principles of patent law ⁸, the court may find infringement of an existing patent either as a result of literal infringement or under the doctrine of equivalents. To determine whether literal infringement has occurred, "resort must be had in the first instance to the words of the claim. If accused matter falls clearly within the claim, infringement is made out and that is the end of it." Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607 (1950).

On the other hand, infringement under the doctrine of equivalents is an equitable doctrine intended to protect patent holders whose patents are not literally infringed. Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1173 (Fed. Cir. 1993). As the Supreme Court stated, in Graver Tank and Mfg. Co. v. Linde Air Products Co.:

Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect. In determining equivalents, things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be equivalents.

⁸ Note that, as a general principle, district courts should follow Federal Circuit patent decisions because appeals from district court patent cases are taken to the Federal Circuit. Mars, Incorporated v. Nippon Conlux Kabushiki-Kaisha, 24 F.3d 1368, 1371 (Fed. Cir. 1994).

339 U.S. at 609; see also Warner-Jenkinson Company, Inc. v. Hilton Davis Chemical Co., 520 U.S. _____, 117 S. Ct. 1040, 1047 (1997)(quoting Graver Tank). The doctrine of equivalents therefore provides that, even if there is no literal infringement, an accused product infringes if it performs substantially the same function, in substantially the same way, to achieve substantially the same result, as the patented device. See Graver Tank & Mfg. Co., 339 U.S. at 608-609; Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 934 (Fed. Cir. 1987) cert. denied 485 U.S. 961 (1988). Each element contained in a patent claim is deemed material to defining the scope of patented invention. Thus the doctrine of equivalents must be applied to individual elements of claim, not to the invention as a whole. Warner-Jenkinson, 117 S. Ct. at 1049. The finding of equivalence is a determination of fact, Graver Tank, 339 U.S. at 608, and may be shown by the testimony of experts. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 761 (Fed. Cir. 1984).

In the case at bar, Merck argues that Mylan's generic formula infringes on its SINEMET CR product through the doctrine of equivalents. Mylan's defense to this charge is twofold: (1) it contends that the prior art prevents Merck from extending either its '957 patent or its '755 patent to encompass Mylan's product; and (2) it argues that the prosecution history estoppel for Merck's patents bars Merck from obtaining coverage of Mylan's formulation. The Court will address each of Mylan's theories of defense in turn.

B. The Prior Art Restriction

1. The General Law

"[T]he prior art restricts the scope of equivalency that the party alleging infringement under the doctrine of equivalents can assert." Conroy v. Reebok Intern., Ltd., 14 F.3d 1570, 1576 (Fed. Cir. 1994); see also International Visual Corp. v. Crown Metal Mfg. Co., Inc., 991 F.2d 768, 772 (Fed. Cir. 1993). Behind this doctrine lies the principle that "a patentee should not be able to obtain under the doctrine of equivalents coverage which he could not lawfully obtained from the PTO by literal claims." Wilson Sporting Goods Co. v. David Geoffrey & Associates, 904 F.2d 677, 684 (Fed. Cir.), cert. denied, 498 U.S. 992 (1990). "Thus since prior art always limits what an inventor could have claimed, it limits the range of permissible equivalents of a claim." Id.

The preferred method of ascertaining the prior art's limitation on the doctrine of equivalents, set forth by the Federal Circuit in Wilson Sporting Goods Co. v. David Geoffrey & Associates, is the conceptual analysis of the hypothetical patent claim. See Conroy, 14 F.3d at 1576 (hypothetical claim analysis is a useful methodology because its clear step-by-step process facilitates appellate review). Under this method, the inquiry is twofold. In the initial step, the court must visualize a hypothetical patent claim structured as similar to the patentee's claims, but broad enough to literally cover the accused's device. Wilson, 904 F.2d at 684. The legal question "then becomes

whether that hypothetical claim could have been allowed by the PTO over the prior art." Id. If not, then the patentee should not be able to obtain that coverage in an infringement suit under the doctrine of equivalents. Id. The patentee bears the burden of showing that the hypothetical claim covering the accused device would be neither obvious over the prior art nor anticipated by the prior art. Id. at 685; Stash, Inc. v. Palmgard Int'l, Inc., 937 F. Supp. 531, 537 (D. Md. 1996).⁹

Obviousness and anticipation are both legal doctrines well-defined in patent jurisprudence. Ultimately, though, obviousness is a question of law, Richardson-Vicks, Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997), and anticipation is a question of fact. In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986).

Section 103 of 35 U.S.C. defines obviousness as follows:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

In considering a claim of obviousness, the court must determine: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art and (3) the level

⁹ As the court stated in Wilson, "[t]he patent owner has always borne the burden of proving infringement, and there is no logical reason why that burden should shift to the accused infringer simply because infringement in this context might require an inquiry into the patentability of a hypothetical claim." 904 F.2d at 685.

of ordinary skill in the art. Glaverbel Societe Anonyme v. Northlake Mktg & Supply, Inc., 45 F.3d 1550, 1555 (Fed. Cir. 1995), citing Graham v. John Deere Co., 383 U.S. 1 (1966). On the other hand, anticipation of a claim, under 35 U.S.C. §. 102¹⁰, occurs only if each and every element as set forth in the

¹⁰ 35 U.S.C. § 102 states:

A person shall be entitled to a patent unless--

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

claim is found, either expressly or inherently, described in a single prior art reference. Verdegaal Bros., Inc. v. Union Oil Company of California, 814 F.2d 628, 631 (Fed. Cir. 1987), cert. denied, 484 U.S. 827 (1987); see also Lindemann Maschinenfabrik GMB v. American Hoist and Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984)("[i]n deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history and identify corresponding elements disclosed in the allegedly anticipating reference.").¹¹

¹¹ Notably, while the hypothetical claim analysis provides ease of application and review, "nothing in Wilson mandates its use as the only means for determining the extent to which the prior art restricts the scope of equivalency that the party alleging infringement under the doctrine of equivalents can assert." Conroy, 14 F.3d at 1576; see also International Visual Corp. v. Crown Metal Mfg Co., Inc., 991 F.2d 768, 772 (Fed. Cir. 1993); Key Mfg. Group, Inc. v. Microdot, Inc., 925 F.2d 1444, 1449 (Fed. Cir. 1991). In using a method other than the hypothetical claim analysis, a court must "apply standards of patentability consistent with our jurisprudence regarding anticipation and obviousness." Conroy, 14 F.3d at 1577. Additionally, the court must keep in mind the fundamental purpose behind such an evaluation which is to prevent the patentee from "'obtain[ing], under the doctrine of equivalents, coverage which [the patentee] could not lawfully have obtained from the [Patent and Trademark Office] by literal claims.'" Id. quoting Wilson Sporting Goods, 904 F.2d at 684.

Merck argues that use of the hypothetical claim analysis under Wilson Sporting Goods is not required and may be more burdensome as a means of evaluation. See Albert B. Kimball, Jr., "Hilton Davis: Practical Implications and Emerging Issues", 507 PLI/Pat 845, 860 (1998). However, at oral argument, Merck conceded that the use of the Wilson hypothetical is not improper. Therefore, in the absence of any persuasive reason why the Court should not do so, the Court will apply this method as the most helpful, step-by-step process in the analysis of this complex matter.

2. Analysis of the Parties' Claims

a. Hypothetical Claim Construction

In compliance with Wilson Sporting Goods, the first step in analyzing an asserted limitation on use of the doctrine of equivalents through the prior art is development of a proper hypothetical claim. Such a hypothetical should be structured to be similar to the patentee's claims, but broad enough to literally cover the accused's device. Wilson Sporting Goods, 904 F.2d at 685.¹²

Looking initially at the patentee's invention, Merck's '755 patent claims the following:

A controlled release oral dosage formulation comprising a uniform dispersion of 25-100 mg of carbidopa and 100-400 mg of levodopa in a polymer vehicle comprising 5-25 mg of a water-soluble hydroxypropylcellulose polymer and 2-50 mg of a less water-soluble polyvinylacetatecrotonic acid copolymer whereby, following administration, the carbidopa and levodopa are released slowly and simultaneously from the formulation.

DE at A12.¹³ The proper hypothetical claim then requires two

¹² Merck argues that Mylan has no support for its statement that a hypothetical Wilson claim formulation be cast in particular terms and that as few changes as possible be made to the literal claim to cover the accused device. To the contrary, Wilson itself suggests that the hypothetical only reflect changes to the patent-in-suit which are necessary to cover the accused product. Wilson Sporting Goods, 904 F.2d at 685; see also DePaul v. Toshiba Corp., 1995 WL 489567, *13 (S.D.N.Y. Aug. 15, 1995) ("the Federal Circuit proposes that the court visualize a hypothetical claim, just sufficient in scope to have the accused product literally infringe.").

¹³ Note that Merck's '957 patent-in-suit discloses the identical elements plus a dye and lubricant. Therefore, for ease of discussion, the Court will focus on the '755 patent with the

changes to this patent-in-suit. The first modification must occur in the amount of HPC. Because Merck's formulation has 5-25 mg of HPC and Mylan's generic uses 29.3 mg of HPC, the hypothetical must cover a range of 5-29.3 mg of HPC. Second, Merck's formulation contemplates using 2-50 mg of a less water-soluble PVACA copolymer, whereas Mylan's discloses 12.8 mg of a water-soluble hydroxypropylmethylcellulose polymer (HPMC). Thus, the hypothetical should read as follows:

A controlled release oral dosage formulation comprising a uniform dispersion of 25-100 mg of carbidopa and 100-400 mg of levodopa in a polymer vehicle comprising 5-29.3 mg of a water-soluble hydroxypropylcellulose polymer and 2-50 mg of a less water-soluble polyvinylacetatecrotonic acid copolymer or a water-soluble hydroxypropyl methylcellulose polymer whereby, following administration, the carbidopa and levodopa are released slowly and simultaneously from the formulation.

At this juncture, the parties' contentions clash. Merck's submitted hypothetical claims include one additional characteristic - the element of being nonhydrodynamically-balanced (i.e. nonfloating). PE at B36-B37. Merck insists that because the Sheth '235 patent floats and both Merck's and Mylan's formulas do not, the nonfloating characteristic must be included in the appropriate hypothetical. To the contrary, Mylan argues

understanding that all conclusions apply identically to the '957 patent.

Additionally, because all of the dependent claims of each of the patents-in-suit contain all of the limitations of each of the independent claims, the opinion will discuss only the independent claims. See Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1552, n.9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim.").

that, because neither Merck's patents nor Mylan's formulation place a limitation concerning the ability or inability to float, the hypothetical claim cannot contain any such limitation.

Turning first to the documentation and the actual claims, it is clear that the nonfloating limitation is not cited in the patents. While a party may not employ a hypothetical claim that eliminates a limitation on the patented claim found in the prosecution history, Judin v. United States, 27 Fed. Cl. 759, 790 (1993), citing Perkin-Elmer Corp. v. Westinghouse Electric Corp., 822 F.2d 1528, 1532-33 (Fed. Cir. 1987), nothing in Merck's patents indicates a nonfloating limitation in its formula. It is well settled that the claims define the claimed invention and, therefore, it is the actual claims that must be anticipated. Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir.) cert. denied 488 U.S. 892 (1988); see also Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1053 (Fed. Cir.), cert. denied 488 U.S. 825 (1988). Unlike the Sheth '235, which specifically claimed a "hydrodynamically based controlled release" formula, DE at A20 (emphasis added), Merck maintained broader coverage of its patents as simply a "controlled release" formulation. DE at A12. Courts cannot alter what the patentee has chosen to claim as his invention. SSH Equipment v. U.S. Int'l Trade Comm'n, 718 F.2d 365, 378 (Fed. Cir. 1983). Even assuming that, while not claimed, the nonfloating restriction is inherent in the product and defined by the specifications, "[p]articular embodiments appearing in the specifications will

not be read into the claims; examples are not what is patented." WeatherChem Corp. v. J.L. Clark, Inc., 937 F. Supp. 1262, 1279 (N.D. Ohio 1996), citing Shamrock Technologies, Inc. v. Medical Sterilization, Inc., 903 F.2d 789, 792 (Fed. Cir. 1990); see, e.g., Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988)(patent claiming use of plasticizers interpreted by the court to have no limitation on whether they must be internal or external even though all given examples show external plasticizers).

To bolster its argument, Merck offers the opinion of its expert, Dr. Joseph Robinson, who notes Sheth's express teaching that its formulation must be hydrodynamically balanced. While Dr. Robinson does say that Merck's tablet has the "inherent physical property" of being nonhydrodynamically balanced, he never professes that the formula teaches that the tablet must be nonfloating or that its nonfloating characteristic is, in any sense, an element of the claim.¹⁴ PE at B18. In fact, Dr. Robinson stated unequivocally in his deposition that "there's nothing in [Merck's patent specification] that specifically tells them not to make a floating tablet." SDE at SA333. Patent jurisprudence instructs that the Wilson hypothetical is to be developed only on the basis of the claims contained in the

¹⁴ As an additional note, the expert report of Dr. Robinson does not utilize a Wilson Sporting Goods hypothetical, which is perfectly acceptable in patent jurisprudence. As such, his opinion is based on a direct comparison of the Merck and Mylan formulations with Sheth '235.

patent-in-suit and the accused product. See, e.g., Shamrock Technologies, supra at p.18; Specialty Components, supra at p.18. Merck fails to point to any authority which supports the contrary proposition that physical characteristics of the products, which are not part of the claim, should be added or removed depending on the physical distinctions of the prior art.

Merck's prosecution history is also revealing on this issue. See Specialty Components, 845 F.2d 981, 987 (Fed. Cir. 1988) (prosecution history is still another tool for claim construction). Throughout the many years Merck appeared before the PTO on this matter, Merck never, when attempting to distinguish the Sheth '235 patent, specifically pointed to the floating/nonfloating distinction. Merck counters that it did, in fact, state to the PTO that the "design of the [Sheth] formulation and the components thereof differ from those of the present claims," DE at A295, which "would certainly encompass the floating issue." Response at 25.¹⁵ However, such a broad and general assertion simply does not support Merck's contention that it did point to the floating/nonfloating distinction while before the PTO. This is especially true when the broad and general assertion is viewed in context, and in light of the sentences immediately following it, which specifically

¹⁵ Oddly, despite its comments that it distinguished Sheth on the floating issue, Merck later argues that it never said anything about floating. Specifically, in its brief, it states: "[h]ad Merck tried [to obtain claims literally covering Mylan's formula], it might well have said something about floating." Response at 26.

distinguished Sheth, not on the basis of the floating/nonfloating characteristics, but rather on the basis of the polymers used.¹⁶ As Merck claimed its invention so as not to include the floating/nonfloating limitation, it cannot now argue that such a limitation should be included in the hypothetical claim as a means of avoiding a prior art defense.¹⁷

¹⁶ Merck argues that if Sheth did indeed anticipate Merck's claims, the patent examiner would have so cited it - which it did not. Rather the basis for the rejection was obviousness - more specifically from the combination of the controlled release concept of levodopa and carbidopa of the Sheth, Fix and Bagli patents with the polymer vehicle of Schor. Therefore, Merck needed only to modify its polymer vehicle so as not to fall within Schor's coverage. Interestingly, however, when Merck later sought to distinguish its claimed invention from Sheth, it cited, not the fact that Sheth was nonhydrodynamically-based and, thus, distinct, but rather the differences in the elected polymer vehicles used by the two formulations. PE at A295. Moreover, the fact that the patent examiner said nothing about the Schor patent's nonfloating structure rendering Merck's formula obvious indicates that the nonfloating property was not an element of the claim.

Additionally, Merck's contends that, if Sheth anticipated Mylan's formulation, the patent examiner should have found such an anticipation against Merck's originally filed claims which, according to Mylan, also literally covered Mylan's formulation. Such an argument is baseless. Merck's original claims described a very broad range of polymer vehicles which encompassed those employed by Mylan's formula. The Sheth '235 patent did not cover such a broad range of polymers.

¹⁷ Although not having the force of preclusion, Merck's statements to the New Zealand Patent Office are instructive in this regard. Tanabe Seiyaku Co. v. United States Int'l Trade Comm'n, 109 F.3d 726, 733 (Fed. Cir.), cert. denied, 118 S. Ct. 624 (1997) (statements to foreign patent offices should be considered when they constitute relevant evidence). Merck did point out that "the formulation described in [Sheth '235] is designed to float on the gastric fluids while their contents are slowly released. This mechanism is quite different from the mechanism employed in the present invention for slow and simultaneous release of the carbidopa and levodopa from the formulation." PE at A34. However, it immediately went on to state that they

Finally, nothing in Mylan's formulation indicates that its product has a nonfloating limitation which needs to be added to the hypothetical. Rather, Mylan broadly describes a controlled release formula with 50 mg of carbidopa and 200 mg of levodopa combined in 29.3 mg of HPC and 12.8 mg of HPMC. DE at A14-15. Although it does not contain any of the edible, fatty materials that will cause the product to float, the formulation does not have an express or inherent preclusion of floating.

In summary, the understanding of the art and the prosecution history show that the "controlled release formula" cited in Merck's patent is not restricted to nonfloating tablets. Merck, therefore, has failed to point to any language, either in its own patents or in Mylan's formulation, indicating that the nonfloating characteristic is, in fact, an element of the claims. Because a dispute as to the legal issue of claim construction does not bar summary judgment, Martin v. Barber, 755 F.2d 1564,

concede that the cited U.S. patent specification [Sheth '235] discloses controlled release compositions which contain levodopa and a decarboxylase inhibitor and which comprise a mixture of the active ingredients with one or more hydrophylic hydrocolloids. . . . It can, therefore, be argued that the [Sheth '235 patent] discloses controlled release oral dosage formulations within the scope of present claim 1 comprising a uniform dispersion of carbidopa, levodopa and optionally a tablet lubricant and/or pharmaceutically acceptable dye in a polymer vehicle comprising up to 120 mg of a water soluble polymer selected from 'hydroxy-propyl cellulose, hydroxypropylmethyl cellulose . . . and methyl cellulose.'

PE at A34. As such, Merck chose to restrict the claims by limiting the polymers used, thereby suggesting that the nonfloating characteristic was not a restriction on its invention.

1567 (Fed. Cir. 1985), construction of the hypothetical is well within the court's province. See Intellical, Inc. v. Pharmetrics, Inc., 952 F.2d 1384, 1387 (Fed. Cir. 1992) ("[c]laim interpretation is a question of law amenable to summary judgment"). Consequently, based on the uncontradicted facts, the Court concludes that the hypothetical should not include the nonfloating limitation.

b. Anticipation Analysis

The next step in the evaluation of this dispute mandates a determination of whether the prior art anticipates the hypothetical.¹⁸ As taught by the Federal Circuit, if a single piece of relevant prior art contains all the elements of the patent at issue, the prior art is said to have anticipated the patent. See Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715-16 (Fed. Cir. 1984).

The Sheth '235 patent expressly claims: (1) a hydrodynamically based controlled release; (2) comprising carbidopa and levodopa in a ratio ranging from about 4:1 to about 10:1 and (3) in percents by weight based on the total weight of the composition, from about 5% to about 80% of a hydrocolloid or mixture of hydrocolloids section from a group containing, inter alia, hydroxy-propyl methylcellulose and hydroxypropylcellulose. DE at A16-21. When used in capsule or tablet form, the formula

¹⁸ While analysis under Wilson Sporting Goods would require an examination as to whether the prior art anticipates or makes obvious the hypothetical claim, defendant has limited its argument to the anticipation prong.

is hydrodynamically balanced so that, upon contact with gastric fluid, said tablet remains buoyant in the gastric fluid of the stomach until substantially all of the active ingredients contained therein have been released. DE at A16-21. Referencing this claim, Mylan argues that the Sheth '235 patent discloses each and every element of the proper hypothetical claim, either expressly or inherently and, thus anticipates.

Merck disputes this conclusion and argues, on several grounds, that no such anticipation has occurred. First, regardless of whether the nonfloating limitation is included in the hypothetical, it contends, by way of its expert report, that, because Sheth '235 expressly teaches that it is essential for its formula to be hydrodynamically balanced, Sheth cannot be read to disclose a sinking tablet such as Merck's product and Mylan's generic. PE at B18. However, this argument misapplies the doctrine of anticipation which only requires that each and every element of the hypothetical claim be found "either expressly or inherently described, in a single prior art reference."

Verdegaal Bros., 814 F.2d at 631; see also Celeritas Technologies Ltd. v. Rockwell International Corp., 47 U.S.P.Q.2d 1516, 1998 WL 401500 (Fed. Cir. 1998) ("the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis."). As discussed above, the hypothetical need not disclose each and every element of that prior art. Therefore, the mere fact that the identified hypothetical in this matter fails to disclose Sheth's express requirement of being

hydrodynamically balanced merely demonstrates that such a hypothetical would not infringe on the Sheth patent and, therefore, is of no consequence in the present analysis.

Second, Merck asserts that Sheth's broad language disclosing a vast array of combinations of HPC and HPMC does not place a person skilled in the art in possession of the hypothetical claim having a polymer vehicle comprising 29.3 mg of HPC and 12.8 mg of HPC. It claims that, because there is no express disclosure in Sheth of Mylan's generic, Mylan must rely on alleged "inherent" disclosures derived from various broad statements within Sheth. According to Merck, The references relied on for "inherent disclosures" do not support Mylan's claims. For example, Mylan cites Sheth's language of 5% to 80% of a hydrocolloid or mixture of hydrocolloids selected from an identified group as disclosing 29.3 mg of HPC and 12.8 mg of HPMC. Merck contends that this broad language does not place a person skilled in the art in possession of Mylan's formula. Minnesota Mining and Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1572 (Fed. Cir. 1992) ("In order to anticipate, the [prior art] must sufficiently describe the claimed invention to have placed the public in possession of it.").¹⁹

¹⁹ Minnesota Mining and Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1572 (Fed. Cir. 1992) is distinguishable. In that case, the court found that the prior art's broad statement that fiberglass could be used as a substrate did not disclose the ranges of fiberglass claimed in the patent-in-suit. To the contrary, Sheth '235 discloses a range of amounts of HPC and HPMC into which the claimed amounts of HPC and HPMC of the hypothetical unmistakably falls.

Again, these arguments fail on several grounds. First, under the hypothetical claim analysis, the appropriate comparison is between the prior art and the hypothetical claim, not between the prior art and the accused product. Merck, however, states that Sheth does not disclose the specific amounts of 29.3 mg HPC and 12.8 mg HPMC found in Mylan's generic. To the contrary, the hypothetical claim contains a range of 5-29.3 mg HPC and 12.8 mg HPC. Therefore, the amounts which must be anticipated are amounts disclosed in the hypothetical.

Furthermore, beyond the blanket conclusion that the language of Sheth does not disclose these ranges of HPC and HPMC, Merck fails to raise any genuine issue of material fact as to Mylan's factually established proposition that Sheth inherently discloses these amounts. Contrary to Merck's arguments that there must be specific disclosure, anticipation may occur by inherent disclosures. Glaverbel, 45 F.3d at 1554; Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369 (Fed. Cir. 1991), cert. denied, 506 U.S. 817 (1992). To constitute an inherent anticipation, an undisclosed element must necessarily be present in a structure described by the prior art. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268-69 (Fed. Cir. 1991). Undisputedly, Sheth discloses an HPMC combination which comprises anywhere from 5% to 80% of the composition. In a 300 mg tablet with 5-29.3 mg of HPC and 12.8 mg of HPMC, the combination of the two would range from 5.9% to 14% - well within

the range disclosed by Sheth.²⁰ Having pointed to nothing which controverts this fact, Merck's contentions cannot withstand summary judgment.²¹

Finally, Merck asserts that, contrary to Mylan's statements, Sheth does not explicitly disclose 50 mg of carbidopa with 200 mg of levodopa. The passages of Sheth identify four possible decarboxylase inhibitors, one of which is carbidopa, and then lists a range of ratios of levodopa to the decarboxylase inhibitor from about 4:1 to about 10:1. DE at A20. Merck maintains that Sheth's failure to specifically identify carbidopa as the preferred decarboxylase inhibitor prevents anticipation. Further it alleges that "[t]hese portions of Sheth do not 'explicitly [disclose] using 50 mg of carbidopa with 200 mg of levodopa,' nor do they suggest the unexpected beneficial results attributable to this particular combination." Response at 29.

However, in contradiction to its claims about Sheth not identifying carbidopa as a preferred decarboxylase inhibitor, Merck conceded to the Patent Office that "Sheth . . . does

²⁰ Additionally, Merck claims that, for anticipation, Mylan's generic would have to be identically disclosed as a whole by Sheth. Response at 6. Such an argument is completely at odds with the Supreme Court's teaching that "the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." Warner-Jenkinson, 117 S. Ct. at 1049.

²¹ The one line statement in Merck's expert report that, "Sheth does not specifically identify . . . (b) the particular amounts of HPC and HPMC to comprise a polymer equivalent to that of SINEMET® CR . . .," adds little weight to Merck's arguments. PE at B18.

describe a sustained-release combination of levodopa and carbidopa." DE at A295. Moreover, while the actual claim of Sheth does not disclose the exact amounts of carbidopa and levodopa, the given examples within the Sheth patent are certainly sufficient to "[place] a person of ordinary skill in the field of the invention in possession of [these amounts]." Motorola, Inc. v. Interdigital Technology Corp., 121 F.3d 1461, 1473 (Fed. Cir. 1997), citing In re Spada, 911 F.2d 705, 708 (Fed. Cir.1990); see also Continental Can Co., 948 F.2d at 1268. More specifically, the example describes a 200 mg levodopa plus 50 mg carbidopa controlled release capsule which mirrors the amounts described by the hypothetical formula. DE at A20. Therefore, inherent anticipation is present.²²

3. Conclusion on the Issue of Prior Art

Under the Wilson Sporting Goods hypothetical claim analysis, Merck has the burden of proving that a hypothetical claim similar to its patents but sufficient to literally cover Mylan's formulation would be patentable over the prior art. Having failed to meet that burden, the range of equivalents for its patents cannot be extended so as to result in infringement by Mylan's product. Therefore, summary judgment in favor of Mylan based on the prior art restriction is appropriate.

²² Again, Merck's expert's brief statement that "Sheth does not specifically identify a) carbidopa as a preferred decarboxylase inhibitor . . ." is insufficient to create a genuine issue of material fact, especially in light of Merck's statements to the Patent Office. PE at B18.

C. Prosecution History Estoppel²³

1. The General Law

The second limitation on the doctrine of equivalents is prosecution history estoppel. This restriction "precludes a patentee from obtaining in an infringement suit patent protection for subject matter which it relinquished during prosecution in order to obtain allowance of the claims." Mark I Marketing Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285, 291 (Fed. Cir. 1995), cert. denied 516 U.S. 1115 (1996). The purpose of this judicially crafted doctrine is to preserve the central "definitional and public-notice functions of the statutory claiming requirement." Warner-Jenkinson v. Hilton-Davis Chemical Co., 530 U.S. ____, 117 S. Ct. 1040, 1049 (1997); see also Wang Labs v. Toshiba Corp., 993 F.2d 858, 868 (Fed Cir. 1993) ("A patent attorney should not be able . . . to choose one course of action within the PTO with the anticipation that [in later litigation] he or she can always choose an alternate course of prosecution in trial before a federal judge.")(quotation omitted).²⁴

Pursuant to the well-settled objective test, the court must

²³ Even though the summary judgment motion is granted on grounds of the prior art, principles of judicial economy dictate that, for purposes of appeal, the issue of prosecution history estoppel must be decided as well.

²⁴ See generally Note, "To Bar or Not to Bar: Prosecution History Estoppel After Warner-Jenkinson," 111 Harv. L. Rev. 2330 (1998).

ask whether a competitor would reasonably conclude from the prosecution history as a whole that particular subject matter was relinquished. Mark I Marketing Corp., 66 F.3d at 291. The issue is "not only what was surrendered, but also the reason for the surrender." Bayer Aktiengesellschaft v. Duphar Intern. Research, 738 F.2d 1237, 1243 (Fed. Cir. 1994). The fact that claims were narrowed does not always mean that the doctrine completely prohibits a patentee from recapturing some of what was initially claimed. Certain reasons for amending, such as indefiniteness or nonenablement rejections, may not give rise to an estoppel. See Litton Systems, Inc. v. Honeywell, Inc., 140 F.3d 1449, 1458 (Fed. Cir. 1998), citing Warner-Jenkinson, 117 S. Ct. 1040 (1997). However, where a patent owner cannot show a reason for the amendment, other than patentability, "a court should presume that the purpose behind the . . . amendment is such that prosecution history estoppel would apply." Warner-Jenkinson, 117 S. Ct. at 1054.

Additionally, "[a]lthough not automatically erecting an estoppel, an amendment made for reasons other than patentability may still give rise to an estoppel." Litton Systems, 140 F.3d at 1458. The Federal Circuit has acknowledged that, "even arguments made during prosecution without amendments to claim language--if sufficient to evince a clear and unmistakable surrender of subject matter--may estop an applicant from recapturing that surrendered matter under the doctrine of equivalents." Id., citing Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 952 (Fed.

Cir. 1993); see also Texas Instruments Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1174-75 (Fed. Cir. 1993).

Therefore, an argument that an applicant surrendered more than necessary to overcome an examiner's rejection is unavailing. See Pharmacia and Upjohn Pharmaceuticals, Inc., ____ F. Supp. ____, 1998 WL 230226, *6 (N.D.W.Va. March 31, 1998).

Finally, other conduct, aside from representations made during the prosecution of the parent application, may also be considered. For example, remarks made during prosecution of a claim not in suit and statements made after the examiner indicated the claims in suit were allowable can limit a patentee's range of equivalents. Hayes Int'l, Inc. v. Jessop Steel Co., 8 F.3d 1573, 1579 (Fed. Cir. 1993). "Thus, an estoppel can be created even when the claim, which is the basis for the assertion of infringement under the doctrine of equivalents, was not amended during prosecution." Id. The application of prosecution history estoppel is a question of law for the judge to resolve. Mark I Marketing Corp., 66 F.3d at 291. However, the scope of the estoppel can depend on factual questions which may be disputed. Hormone Research Found. v. Genentech, Inc., 904 F.2d 1558, 1564 (Fed. Cir. 1990), cert. dismissed, 499 U.S. 955 (1991).

2. Analysis of the Parties' Claims

Mylan asserts that Merck is barred from extending its patents, via the doctrine of equivalents, to cover Mylan's formulation due to two amendments made during its prosecution

history: (1) Merck's alleged surrender of the use of HPMC in its polymer vehicle and (2) Merck's alleged surrender of a range of 26-120 mg HPC. The Court will first review Merck's argument that the doctrine of prosecution history estoppel does not apply and then address each of Mylan's specific contentions regarding the scope of the estoppel.

a. Application of the Doctrine of Prosecution
History Estoppel

On a general level, Merck argues that its election of a species was an amendment made not for reasons of patentability, but rather in response to the patent examiner's restriction requirement under 35 U.S.C. § 121.²⁵ Because a patent examiner's

²⁵ 35 U.S.C. §121 states:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Commissioner may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Commissioner to require the application to be restricted to one invention.

"restriction is not a rejection" but rather an administrative requirement, R2 Medical Sys., Inc. v. Katecho, Inc., 931 F. Supp. 1397, 1438 (N.D. Ill. 1996), turning the amendment into an estoppel would be contrary to the Federal Circuit's mandate that, simply because an applicant chose to file narrow claims, does not mean that applicant cannot later assert a range of equivalents to its claims. Litton, 140 F.3d at 1456. Merck further contends that, had it "chosen voluntarily to file original claims [that were identical to its ultimate patent formula] it would not be estopped, without showing that this was compelled by the prior art, from asserting a range of equivalents to those claims. The same result must follow, here when under § 121, Merck is compelled to elect a single species claim." Response at 19.

Merck's arguments misconstrue the doctrine of prosecution history estoppel. "[L]imiting the claim because of a restriction requirement . . . would not necessarily invoke file history estoppel." Bayer, 738 F.2d at 1243 (emphasis added).²⁶ Rather the court must examine the prosecution history as a whole in making its determination. Wang Laboratories, 993 F.2d at 867. As noted earlier, estoppel can arise from several sources. If a claim was rejected on several grounds and the record shows that an amendment was made for purposes of the prior art, estoppel may apply. See, e.g., Schmidinger v. Welsh, 383 F.2d 455, 465-466 (3d

²⁶ Note that the court in that case declined to conclusively determine whether a restriction made pursuant to 35 U.S.C. § 121 would create prosecution history estoppel. Bayer, 738 F.2d at 1243

Cir. 1967), cert. denied, 390 U.S. 946 (1968). Additionally, "[u]nmistakable assertions made by the applicant to the Patent and Trademark Office (PTO) in support of patentability, whether or not required to secure allowance of the claim, also may operate to preclude the patentee from asserting equivalency between a limitation of the claim and a substituted structure or process step." Texas Instruments, 988 F.2d at 1174.

In the instant matter, the patent examiner rejected Merck's broadest claim for several reasons, including 35 U.S.C. § 103 (obviousness) and 35 U.S.C. § 121 (the restriction requirement). Although Merck argues that its amendment of its claims was pursuant to § 121 and, therefore, not for reasons of patentability, this Court cannot simply disregard the obviousness rejection or the statements made by Merck to the examiner to distinguish the prior art.²⁷ Rather, as stated above, the Court must undertake a close examination, "not only what was surrendered, but also the reason for such a surrender." Bayer, 738 F.2d at 1243. In light of this factual background, Merck's

²⁷ As Mylan points out, Merck's actions undermine its contention that its amendment was made for purposes of 35 U.S.C. § 121. Merck had explained to the patent examiner that "[T]he amendment to independent claim 6 is tantamount to such election as it is limited to only a single species where a Markush group had been presented." DE at A239. Such a statement indicates that the amendment was made both for purposes of overcoming the prior art rejection and to satisfy the restriction requirement. Moreover, Merck stated to the PTO that "[t]he amendment to the claims is an attempt to obviate therefrom the formal rejections found in the parent application." DE at A238 (emphasis added). By using the plural word "rejections", Merck suggests that it was motivated by more than just the section 121 restriction requirement in amending its claims.

blanket arguments that prosecution history estoppel should not be applied are unavailing.²⁸

b. Merck's alleged surrender of HPMC in its
formulation

First, Mylan asserts that the prosecution history reveals that Merck surrendered the use of HPMC in its formula. Reviewing the actual amendments, Merck initially claimed a controlled release carbidopa/levodopa formulation without reference to specific polymers. However, those claims were rejected, in part, as obvious over the prior art, including the Sheth '235 patent. Merck abandoned its claim and limited its new claims to formulations containing a "water soluble polymer" selected from a specifically listed group or a "less water-soluble polymer", again selected from a specifically listed group. Again, the PTO rejected these claims for being, in part, obvious over the prior art including Sheth '235. Upon abandoning these claims, Merck then narrowed its claims to require specific amounts of carbidopa and levodopa. Mylan further contends that, just prior to the PTO ruling, Merck filed a preliminary amendment and further narrowed

²⁸ Additionally, Merck's argument that, had it originally filed narrow claims it would not be estopped, is inconsequential in the analysis. Rather, prosecution history estoppel looks not to what could have been filed, but what actually was filed and surrendered. It prevents a patent owner in an infringement suit from obtaining a construction of a claim that would resurrect subject matter surrendered before the PTO. Hughes Aircraft, 717 F.2d at 1362. "In other words, if during the prosecution of a patent an applicant is forced to admit, 'my invention is not that,' he may later be estopped from claiming that the invention is that." Slater Electric, Inc. v. Thyssen-Bornemisza, Inc., 650 F. Supp. 444, 455 (S.D.N.Y. 1986).

its claims to require the two specific polymers of PVACA and HPC, thereby surrendering its claims to the other five polymers specified in the water soluble polymer group and to the other eight polymers specified in the less water soluble polymer group. After the amendment, Merck's broadest claim covered only a formulation containing both 5-25 mg of HPC and 2-50 mg of PVACA. It was based on these amendments, that the PTO issued the '957 patent-in-suit.

Following the issuance of this patent, Merck made an additional attempt to obtain broad coverage of the controlled release carbidopa/levodopa formulation. To that extent, Merck submitted claims identical to those contained in the second application. Upon having these claims rejected by the PTO, Merck refined its claims to match the '957 patent. Merck then made arguments to the PTO that its invention was limited to a formula containing both PVACA and HPC as follows:

Sheth et al (U.S. Patent 4,424,235) does describe a sustained-release combination of levodopa and carbidopa, but the design of the formulation and the components thereof differ from those of the present claims. A single polymer is used in the Sheth formulation selected from a natural gum, methyl cellulose, hydroxypropylmethylcellulose [HPMC], hydroxypropylcellulose [HPC] and sodium carboxymethylcellulose. The claimed formulation is a combination of hydroxypropylcellulose [HPC] and polyvinylacetatecrotonic acid copolymer [PVACA]."

DE at A295. Merck also sought to distinguish the Schor '393 patent and stated that Schor "does not suggest the combination of [HPC] and [PVACA] as presently claimed." DE at A296. Pursuant to these representations the '755 patent was issued. Mylan

contends that, based on the prosecution history, it is indisputable that Merck surrendered the HPMC and HPC polymer vehicle.

Merck counters that the amendment of the formula to require use of only HPC and PVACA was not made for reasons of patentability, but rather pursuant to the examiner's restriction requirement under section 121. It alleges that, since none of the prior art required Merck to forego claims covering Mylan's formulation, its election cannot be read to surrender any claims having Mylan's polymer vehicle. Moreover, one of skill in the art would not read its statements to the patent office as giving up claims to Mylan's formulation. See Litton, 140 F.3d at 1462 (standard for applying prosecution history estoppel is whether one of ordinary skill in the art would objectively conclude that an applicant surrendered subject matter).

Once again, Merck's arguments are unavailing. Undoubtedly, the patent examiner rejected Merck's claims, in part, as being obvious over the prior art including the Sheth and Schor patents. Merck repeatedly narrowed its claims from a broad coverage of any polymers to a very specific combination of HPC and PVACA. Its contention that its amendments were made pursuant to the restriction requirement, and were, in no way, required for reasons of patentability, is contradicted by its own assertion, in its submissions to this Court, that "[t]he examiner plainly stated in the second quoted sentence that what he viewed as 'obvious' was to use the polymer vehicle of Schor, not Sheth, to

obtain a controlled release of carbidopa and levodopa." Response at 7. Merck continues on to note that "it was the controlled-release polymer vehicle of Schor . . . that raised an obviousness issue for the examiner and was the basis for his obviousness rejection." Response at 8. Even if that determination by the examiner was incorrect or Merck did not need to give up as much as it did,²⁹ the fact remains that its amendments were made, at least partially, for patentability purposes. Regardless of whether, in hindsight, Merck abandoned too much to obtain its patents, it must now face the limitations imposed on its claims by the abandonments. See Schmindinger, 383 F.2d at 465 (3d Cir. 1967).

Moreover, Merck fails to explain its unequivocal statements to the patent office. First, after obtaining the narrow '957 patent and making a second attempt to gain broad coverage of a controlled release formula of carbidopa and levodopa, Merck clearly expressed to the patent office that Sheth disclosed a different polymer vehicle - one containing a polymer selected from natural gum, methyl cellulose, HPMC, HPC and sodium carboxymethylcellulose - than that found in the claimed formulation which combined HPC and PVACA. DE at A295. Second, it emphasized that "Schor does not suggest the combination of

²⁹ Merck contends that, because Schor covers only a very particular polymer vehicle and does not describe Mylan's polymer vehicle, it would have only needed to eliminate the specific polymer vehicle disclosed in Schor from the scope of its claims. Plaintiff's brief at 8.

[HPC] and [PVACA] as presently claimed as a vehicle for any medicament." DE at A296. "Arguments and amendments made to secure allowance of a claim, especially those distinguishing prior art, presumably give rise to prosecution history estoppel." Wang Laboratories, Inc. v. Mitsubishi Electronics America, Inc., 103 F.3d 1571, 1577 (Fed. Cir.), cert. denied, 118 S. Ct. 69 (1997). The fact that the statements were made after the issuance of the '957 patent does not strip them of their preclusive effect. Haynes Int'l Inc., 8 F.3d at 1579; Hormone Research Foundation, Inc., 904 F.2d at 1564, n.9. Additionally, any suggestion that the statements were made for reasons other than patentability is inconsequential. Litton, 140 F.3d at 1458 ("[I]f an applicant makes an amendment unrelated to patentability which evinces an unmistakable surrender, that action will preclude recapture of the surrendered subject matter under the doctrine of equivalents.").

In summary, one skilled in the art could easily conclude that Merck abandoned any claim to a polymer vehicle identical to that found in Mylan's formulation. Not only do its amendments indicate surrender of such a claim, but its statements affirm that the changes were made for patentability purposes. See Litton Systems, 140 F.3d at 1462 (where an applicant makes arguments in combination with an amendment, the scope of estoppel is a product of the effects of both factors working in concert). The plain meaning of the public record unambiguously reveals that Merck narrowed its claims to relinquish use of an HPC/HPMC

polymer. As such, it cannot now use the doctrine of equivalents to obtain coverage of that product.³⁰

c. Merck's Alleged Surrender of 29.3 mg of HPC

Mylan finally asserts that prosecution history estoppel precludes Merck from asserting that the amount of HPC in Mylan's product is equivalent to Merck's claimed 5-25 mg HPC limitation. In Merck's original claims, it originally sought coverage of formulations containing between 0 and 120 mg HPC limitation. Following rejections of obviousness over the prior art, Merck limited its claim to cover only 5-25 mg of HPC. In turn, Mylan now argues that Merck surrendered coverage of formulations containing between 25 mg and 120 mg of HPC and is thereby estopped from asserting that Mylan's product, which contains 29.3 mg of HPC, infringes under the doctrine of equivalents.

Merck merely responds that no prior art required Merck to limit its claims to 5-25 mg of HPC and no estoppel could arise from Merck's statements to the Patent Office. "The threshold

³⁰ The report of Dr. Robinson, Merck's expert, does very little to bolster Merck's position. Dr. Robinson merely reiterates the arguments of Merck's brief which, as discussed above, is contrary to the public record. "A patentee may not proffer an interpretation for the purposes of litigation that would alter the indisputable public record consisting of the claims, the specification and the prosecution history, and treat the claims as a 'nose of wax.'" Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir.), cert. denied, 516 U.S. 987 (1995), quoting Senmed, Inc. v. Richard-Allan Med. Indus., Inc., 888 F.2d 815, 819 n. 8 (Fed. Cir. 1989)); see also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper.").

fatal flaw," as argued by Merck, "is that Mylan has cited to no prior art which would have required Merck to limit its claims to 5-25 mg in order to obtain a patent." Response at 23.

Merck's argument improperly shifts the burden to Mylan. As the Supreme Court has noted, the burden is on the patentee to establish the reason for an amendment made during prosecution which is sufficient to overcome prosecution history estoppel. Warner-Jenkinson Co., Inc., 117 S. Ct. at 1051. Where a patent owner cannot state a reason for the amendment other than patentability, the court should presume that the reason is such that prosecution history estoppel would apply. Litton Systems, 140 F.3d at 1456, citing Warner-Jenkinson, 117 S. Ct. at 1051. Consequently, Merck's statement that Mylan failed to cite to any prior art which would have required limitation of the amount of HPC used mistakenly places the burden on Mylan to do so. Absent any reason for the amendment and pursuant to the dictates of the Supreme Court in Warner-Jenkinson, the Court must presume that Merck limited its formulation for reasons of patentability and thereby surrendered any claims to a formula containing between 25 and 120 mg of HPC. As Mylan's formula contains 29.3 mg of HPC, prosecution history estoppel bars Merck from obtaining coverage of that product through the doctrine of equivalents.

3. Conclusion on the Issue of Prosecution History Estoppel

Based on the foregoing analysis, Merck has surrendered coverage of (1) a polymer vehicle comprised of HPC and HPMC and

(2) a formulation containing anywhere from 25 to 120 mg of HPC. As Mylan's generic contains the HPC/HPMC polymers and 29.3 mg of HPC, Merck is estopped from asserting that this generic infringes on its patents under the doctrine of equivalents. In light of this surrender, Mylan's Motion for Summary Judgment on the grounds of prosecution history estoppel must be granted.

V. CONCLUSION

Mylan has established a basis for summary judgment on two grounds. Specifically, it has shown that both (1) the prior art doctrine and (2) prosecution history estoppel limit the scope of Merck's patents. As a result of these limitations, Merck is precluded from asserting infringement by Mylan's product under the doctrine of equivalents. Therefore, summary judgment will be granted in favor of Mylan and against Merck on both theories.

An appropriate order follows.